



ATTORNEY DOCKET NO. 600-69-CIP

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)

Jayasree Vasudevan)

Serial No.: 10/656,715)

Filed: September 05, 2003)

For: COMPOSITIONS AND)
METHODS USING COMPOUNDS)
HAVING CYTOCHROME P450RAI)
INHIBITORY ACTIVITY CO-)
ADMINISTERED WITH VITAMIN)
A)

Examiner: Amy Lewis

Group Art Unit: 1614

Anaheim, California

Certificate of Mailing

I hereby certify that this correspondence is being deposited on 9.15.06 with the United States Postal Service as first class mail in an envelope addressed to Mail Stop Non-Fee Amendment Commissioner of Patents, P.O. Box 1450, Alexandria Virginia, 22313-1450


Toni Whyte

September 15, 2006
Date

DECLARATION OF JAYASREE VASUDEVAN Ph.D.

I, Jayasree Vasudevan hereby declare as follows.

1. I have a Doctor of Philosophy degree in chemistry received in 1994 from the Indian Institute of Chemical Technology, Hyderabad India. My Ph. D. thesis involved the "Synthesis of Some Biologically Active Compounds".

After obtaining my Ph. D. degree I was post-doctoral research fellow in the department of Chemistry at Rutgers, the State University of New Jersey. From September 1997 until approximately April 2004 I was a research scientist, with steadily advancing titles, in the Retinoid Research Department of Allergan Inc. of Irvine California. During these years I acquired substantial experience and knowledge regarding compounds of the “retinoid” type and of compounds which inhibit the catabolic breakdown of retinoids, as well as their mode of actions and potential applications in human and veterinary medicine. My work at Allergan resulted in numerous research publications in peer-reviewed scientific journals and in numerous United States and foreign patents. Since approximately May 2004 to the present I have been working at Vitae Pharmaceuticals in connection with the development, including their regulatory approval, of retinoids and of CP450RAI inhibitors for use in human medicine. As a result of the foregoing experience I consider myself an expert, and am an expert regarding retinoid and related compounds and their potential use in medicine. For a more detailed description of my educational and research experience I refer to my Curriculum Vitae which is attached here as **Exhibit 1**.

2. I am of the expert opinion that the above-identified application for patent adequately discloses to a person of ordinary skill in the art the subject matter of its claims, namely that the compounds described in the application and defined in the claims can be co-administered with other “retinoids” (including vitamin A, retinoic acid or other compounds having retinoic acid like “retinoid’ activity) to treat those diseases or conditions which are known or recognized to be treatable by retinoids. A person of ordinary skill in the art of using “retinoids’ will readily recognize that co-administration with the

compounds of the claims is likely to result in increased effectiveness of the retinoid because, due to the inhibition of the enzyme CP450RAI, the retinoid reaches higher or more longer lasting concentrations in the body. In my opinion it will not require undue experimentation to see in which specific disease the claimed methods of co-administration are useful.

3. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 14th September, 2006

Jayasree Vasudevan

Jayasree Vasudevan Ph. D.